

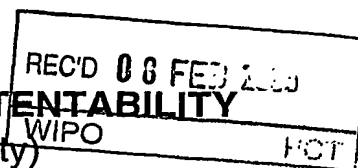
PATENT COOPERATION TREATY


PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference P16657PC00		FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/SE2004/000070		International filing date (day/month/year) 21.01.2004	Priority date (day/month/year) 21.01.2003	
International Patent Classification (IPC) or national classification and IPC A61M5/32				
Applicant CARMEL PHARMA AB				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 5 sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 06.08.2004		Date of completion of this report 07.02.2005		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Lager, J Telephone No. +49 89 2399-2957		



**INTERNATIONAL PRELIMINARY REPORT
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-12 as originally filed

Claims, Numbers

1-34 received on 24.01.2005 with letter of 21.01.2005

Drawings, Sheets

1/6-6/6 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☒ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☒ the claims, Nos. 35-55
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing *(specify)*:
 - ☐ any table(s) related to sequence listing *(specify)*:
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing *(specify)*:
 - ☐ any table(s) related to sequence listing *(specify)*:

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-34
Inventive step (IS)	Yes: Claims	
	No: Claims	1-34
Industrial applicability (IA)	Yes: Claims	1-34
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Section V.

1. The closest prior art is represented by document EP-A-0 819 442 (=D1) which discloses the technical features, cf. PCT Guidelines chapter IV-7.6, of the independent claims for the following reasons:

1.1 Claim 1.

D1 discloses: a needle (10) suitable for penetrating a membrane, having a pointed end (40) provided with a penetrating tip (20) and with an opening (22) for letting a liquid in and/or out in a main direction (18) which is substantially parallel to the longitudinal extension of the needle (10), the penetrating tip (20) is designed with a substantially point-shaped edge (36) suitable to initially prick a membrane when the membrane is penetrated and that the outer edges (32a,32b) present on the pointed end (36) in the area between the point-shaped edge (36) and a position (30) beyond the opening (22) are rounded such that it is suitable to push a membrane away rather than cutting it.

The subject-matter of claim 1 is therefore regarded not new over the teaching and disclosure of D1 since D1 discloses all technical features of claim 1 contrary to the requirements of Article 33(2) PCT.

1.2 Claim 21.

Claim 21 has the same preamble as claim 1. It differs from claim 1 in the functional definitions of the cross-section and the force distribution.

Any circular needle having a pointed end with a penetrating tip and an opening, i.e. any commonly used needle, would deprive novelty of claim 21 since it will cause **at least three** substantially equally sized forces when penetrating a material. Moreover, a perfect circular needle penetrating a perfect homogeneous material will create infinite number of equally sized forces distributed 360°. Furthermore, it appears that the cross-section distal of points (38a,39b) of the needle of D1 will, or could, create at least three substantially equally sized forces which also depends on the material to be penetrated.

Claims 21 therefore lacks novelty contrary to the requirements of Article 33(2)

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1.3 Claim 24.

The disclosure of forming the needle of D1 on page 3, line 50 - page 5, line 20, appears to be suitable as a method of manufacturing a needle according to claim 24. In D1 the method uses e.g. a grinding wheel to create the form disclosed in the figures of D1. It also discloses turning of the needle during grinding which will automatically lead to that the outer edges becomes rounded as defined in claim 24.

Claims 24 therefore lacks novelty contrary to the requirements of Article 33(2) PCT.

2. Dependent claims 2-20, 22-23 and 25-34 appear not to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (Article 33(2) PCT) or inventive step (Article 33(3) PCT).

The features defined in these claims appear only to be slight constructional changes not involving any novel features or features providing an inventive step.

None of these claims define the essential technical features leading to the embodiments disclosed in figures 1, 2, 6 and 11.

3. In order to overcome the above mentioned objections the applicant should have defined the needle in a single (see Section VIII below) independent "needle" claim (which is novel over D1, provides an inventive step over the teaching of D1 combined with any teaching of the other cited documents and drafted in the two part form against D1) and a method claim defining the steps of manufacturing precisely that needle, i.e. containing a back reference to any of the previously defined needle claims. Such a needle claim and method claim would fulfil the requirements of Article 33(2)-(4) PCT, cf. figures 1, 2, 6 and 11.

Section VIII.

1. Although claims 1 and 21 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter, i.e. overlapping subject-

matter, and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter.

The aforementioned claims therefore **lack conciseness** and as such do not meet the requirements of Article 6 PCT.

Comments to the letter of reply of 21.01.2005.

- The applicant argues that the needle according to claim 1 will act differently when penetrating a membrane than the needle of D1. This is however irrelevant since the membrane is not a part of the needle for which protection is sought in claim 1 and the technical features performing this particular penetration are not defined in claim 1. When having regard to the embodiments of figures 1, 2, 6 and 11 of the present application, the division agrees with the applicant that there is a difference which may cause the particular penetration referred to. However the technical features constituting this difference, i.e. leading to a particular penetration of a membrane, are not defined in claim 1, cf. PCT Guidelines chapter III 4.4. Claim 1 therefore still lacks novelty, Article 33(2) PCT.
- The applicant has added the features of former claim 44 into claim 41 to form the new claim 21, stating that the tip is arranged to lie substantially on the longitudinal centre line of the needle. Tip (20) of D1 certainly lies on the longitudinal centre line of the needle, cf. e.g. figures 2 and 3. It may be that the applicant means something else with the term "tip" than the tip (20) of D1. However this should have been unambiguously clearly defined by the technical features such that no misunderstanding may occur on what is meant by a tip. Claim 21 (former claims 41+44) therefore still lacks novelty, Article 33(2) PCT.
- Claim 24 (former claim 45) does not just lack novelty, Article 33(2) PCT, but also lacks clarity, Article 6 PCT. What kind of needle is manufactured? Does this needle have anything to do with the needle as defined in any of claims 1-23? To make this clear the claim should have had a back-reference to the previously defined needle claims.
Which method step of claim 24 causes the needle to arrive at the configuration of any of figures 1, 2, 6 or 11?
It appears that any manufacture of a needle would deprive novelty of claim 24. A method claim is allowable, should the method itself or the product manufactured

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by the method be new and inventive. However, neither is the case in the present claim 24.

- The applicant has requested "further proceedings" should the IPER become negative.

The applicant has received a so called WO-ISA issued by the Swedish Patent Office acting as ISA. This communication is considered equivalent with a proper Written Opinion (WO or 408). In addition the European Patent Office has issued a Written Opinion dated 23.11.2004.

It is not foreseen that 3 Written Opinions could be issued before the IPER is due.

CLAIMS

- 5 1. A needle (1) for penetrating a membrane (2), having a pointed end (3) provided with a penetrating tip (4) and with an opening (6) for letting a liquid in and/or out in a main direction (7) which is substantially parallel to the longitudinal extension of the needle, **characterized in that** the penetrating tip (4) is designed with a substantially point-shaped edge (8) to initially prick a membrane (2) when the
- 10 membrane is penetrated and that the outer edges (19) present on the pointed end (3) in the area between the point-shaped edge (8) and a position (25) beyond the opening (6) are rounded so that after the initial penetration the pointed end (3) will push the membrane material away rather than cutting the membrane material.
- 15 2. A needle according to claim 1, **characterized in that** the inner edge (21) of the opening (6) is rounded.
- 20 3. A needle according to claim 1 or 2, **characterized in that** the penetrating tip (4) is designed with a cross section (26) having a symmetry causing at least three substantially equally sized forces (F) in different directions which are radial to the longitudinal centre line (5) of the needle and which forces counteract each other so that the needle (1) will tend not to deviate from the initial penetration direction when the needle (1) penetrates a membrane (2).
- 25 4. A needle according to claim 3, **characterized in that** the cross section is substantially triangular with rounded edges.
- 30 5. A needle according to claim 3, **characterized in that** the cross section is substantially circular.
- 35 6. A needle according to any of claims 1-5, **characterized in that** the point-shaped edge (8) of the penetrating tip (4) is arranged to lie substantially on the longitudinal centre line (5) of the needle (1).
7. A needle according to any of claims 1-6, **characterized in that** the pointed end

(3) has a shape substantially corresponding to a part of an imaginary cone, the tip (9) of which coincides with the substantially point-shaped edge (8).

- 5 8. A needle according to any of claims 1-7, **characterized in that** at least a major part of the opening (6) is arranged on one and the same half of the cross section of the needle (1).
- 10 9. A needle according any of claims 1-8, **characterized in that** the pointed end (3) is provided with a basic shape in accordance with a lancet bevel cut.
- 10 10. A needle according any of claims 1-9, **characterized in that** the pointed end (3) is provided with a basic shape in accordance with a back bevel cut.
- 15 11. A needle according to claim 10, **characterized in that** the back bevel cut has a tip angle (α) in the interval 20° to 50° .
12. A needle according to claim 10, **characterized in that** the back bevel cut has a tip angle (α) in the interval 50° to 100° .
- 20 13. A needle according to claim 10, **characterized in that** the back bevel cut has a tip angle (α) in the interval 30° to 80° .
14. A needle according to claim 12 or 13, **characterized in that** the tip angle (α) is approximately 75° .
- 25 15. A needle according any of claims 10-14, **characterized in that** the back bevel cut has a second grind angle (β) in the interval 50° to 140° .
16. A needle according to claim 15, **characterized in that** the second grind angle (β) is approximately 100° .
- 30 17. A needle according to any of claims 1-10, **characterized in that** the needle is provided with a tip angle (α) in the interval 20° to 100° .
- 35 18. A needle according to claim 17, **characterized in that** the tip angle (α) is in the

interval 30° to 80°.

19. A needle according any of claims 1-10, **characterized in that** the needle is provided with a rear angle (β) in the interval 50° to 140°.

20. A needle according to claim 19, **characterized in that** the rear angle (β) is approximately 100°.

21. A needle for penetrating a membrane (2), said needle (1) having a pointed end (3) provided with a penetrating tip (4) and with an opening (6) for letting a liquid in and/or out in a main direction (7) which is substantially parallel to the longitudinal extension of the needle (1), **characterized in that** the point-shaped edge (8) of the penetrating tip (4) is arranged to lie substantially on the longitudinal centre line (5) of the needle (1), and the penetrating tip (4) is designed with a cross section (26) having a symmetry causing at least three substantially equally sized forces (F) in different directions which are radial to the longitudinal centre line (5) of the needle and which forces counteract each other so that the needle (1) will tend not to deviate from the initial penetration direction when the needle (1) penetrates a membrane (2).

22. A needle according to claim 21, **characterized in that** the cross section is substantially triangular with rounded corners.

23. A needle according to claim 21, **characterized in that** the cross section is substantially circular.

24. A method for manufacturing a needle (1) for penetrating a membrane (2), comprising:

cutting a tubular blank (15) obliquely for obtaining a pointed end (3) provided with a penetrating tip (4) and with a opening (6) for letting a liquid in and/or out in a main direction (7) which is substantially parallel to the longitudinal extension of the needle (1),

characterized by providing the penetrating tip (4) with a substantially point-

shaped edge (8), and

rounding all outer edges (19) present on the pointed end (3) in the area between the point-shaped edge (8) and a position (25) beyond the opening (6).

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25. A method according to claim 24, **characterized by** rounding the inner edge (21) of the opening (6).

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26. A method according to claim 24 or 25, **characterized by** shaping the penetrating tip (4) with a cross section (26) having a symmetry causing at least three substantially equally sized forces (F) in different directions which are radial to the longitudinal centre line (5) of the needle (1) and which forces counteract each other so that the needle (1) will tend not to deviate from the initial penetration direction when the needle (1) penetrates a membrane (2).

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27. A method according to any of claims 24-26, **characterized by** arranging the point-shaped edge (8) of the penetrating tip (4) to lie substantially on the longitudinal centre line (5) of the needle (1).

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28. A method according to any of claims 24-27, **characterized by** shaping the pointed end (3) as a part of an imaginary cone, the tip (9) of which coincides with the substantially point-shaped edge (8).

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29. A method according to any of claims 24-28, **characterized by** shaping the pointed end (3) so that at least a major part of the opening (6) will be located on one and the same half of the cross section of the needle (1).

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30. A method according to any of claims 24-29, **characterized by** grinding the penetrating tip (4) in accordance with a lancet bevel cut before rounding the outer edges of the pointed end (3).

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31. A method according to any of claims 24-30, **characterized by** grinding the penetrating tip (4) in accordance with a back bevel cut before rounding the outer edges of the pointed end (3).

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32. A method according to any of claims 24-31, **characterized by** shaping the penetrating tip (4) by a non-cutting process, such as forging, hammering or similar.
- 5 33. A method according to any of claims 24-32, **characterized by** rounding the outer edges (19) by blasting and/or electrochemical polishing.
- 10 34. A method according to claim 25, **characterized by** rounding the inner edge (21) of the opening (6) by blasting and/or electrochemical polishing.
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